REMARKS

The Office Action, mailed March 24, 2003, and Advisory Action, mailed September 26, 2003, have been received and reviewed. Claims 1-5, 10-13, 16-25 and 31-33 are pending and claims 1-5, 10-13, 16-25 and 31-32 stand rejected. All claim amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

The applicants thank the Examiner and her supervisor for the interview conducted August 11, 2003. As acknowledged at the interview, the claim amendments presented herein overcome the rejections under 35 U.S.C. § 112, first paragraph, Paper 14. As discussed at the interview, the claim amendments distinguish the claims over Huang *et al.* and should place the claims in condition for allowance.

Support for Claim Amendments:

Claims 1, 4, 10-13, 16-17 and 22 have been amended without prejudice or disclaimer. Claims 2-9 and 11-32 have been canceled without prejudice or disclaimer. Support for the amendments can be found throughout the specification, for example, on page 6 of the specification. This peptide blocks sensitization of mast cells, for example, on pages 7-9 of the specification.

In addition, support for the amendment of claim 1 can be found throughout the specification, for example, on page 5, lines 23-27 of the specification. To further prosecution of the application, the applicants have removed the term "diluent," which was thought to raise an issue of new matter, and replaced it with the broader term "excipient," so as to provide *ipissima verba* support. However, the applicants submit that the specification supports the term "diluent." For example, on page 5, lines 23-27 of the specification where "a pharmaceutical composition comprising ... a pharmaceutically acceptable carrier or excipient" is described and on page 6 "Preparation 1" where the peptide was precipitated, purified by HPLC, which requires a diluent. Nevertheless, in light of the present amendment, no new matter has been added.

Furthermore, the amendment to claim 10 cited by the Office as raising an issue of new matter was intended to simply spell out "mg/l" and "µg/l." The applicants had, and have, no

intention of changing milligrams per liter (mg/l) to micrograms per liter (μg/l). However, through a typographical error, milligrams per liter was inadvertently submitted in the After final response as "micrograms per liter." The applicants have corrected the typographical error to reflect the original milligrams per liter (mg/l). Should the Office prefer the use of "mg/l" and "μg/l" the Office is kindly requested to contact the applicants representative at the number provided herein. Support for the amendment can be found, for example, in the paragraph spanning pages 4 and 5. Thus, no new matter has been added.

Support for claims 33 and 34 can be found throughout the specification, for example, a pharmaceutical composition comprising a pharmaceutically acceptable carrier or excipient may be found on page 4, line 35 to page 5, line 27 of the specification. Support for bronchial constriction can be found, *inter alia*, in Example 2 on pages 8 and 9 of the specification. Support for the peptide comprising 200 micrograms can be found, *inter alia*, on page 8, lines 25-27 and Example 2 of the specification.

Advisory Action:

Applicants have addressed the issue of new matter under the heading "Support for Claim Amendments." The Advisory Action states that it is not clear which disease states the claimed pharmaceutical composition intends to treat.

The applicants note that a composition claim need not recite its intended use. In addition, the specification provides a non-limiting list of exemplary disease states, for example, page 4, line 35 to page 5, line 15. Furthermore, the Office is directed to the following non-exclusive list of U.S. Patents and their respective claims, which claim pharmaceutical compounds without recitation of an intended use:

U.S. Patent 6,566,116, claim 3 and dependent claim 4;

U.S. Patent 6,518,458 and claim 2;

U.S. Patent 6,509,345, claim 1 and dependent claim 16;

U.S. Patent 6,313,177 and claim 12; and

U.S. Patent 6,214,832 and claim 1.

Thus, applicants submit that a composition claim need not define its intended use and that such uses are clearly laid out in the specification. Furthermore, claim 10 sets out the characteristics of the disease state. Thus, a disease state having the recited characteristics would be amenable to treatment with the claimed compound.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph:

Claims 1-5, 10-13, 16-25 and 31-32 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement commensurate with the scope of the claims. In addition, claims 1-5, 10-13, 16-25 and 31-32 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description.

While the applicants respectfully disagree with the claim rejections based on enablement and written description, as outlined in Paper 13, the applicants have amended the claims without prejudice or disclaimer to facilitate prosecution of the application. As noted by the Examiner, "a pharmaceutical composition consisting of SEQ ID NO:1 and a pharmaceutical[ly] acceptable carrier ... overcome[s] the ... enablement and written description [rejection]." (Paper 14) No new search or consideration is required by the amendment, as the Examiner has indicated that the claims, as amended, are enabled for "a composition comprising a peptide consisting of SEQ ID NO:1," (Paper 13 at page 2), and satisfy the written description requirement since the specification discloses a "peptide consisting of SEQ ID NO:1 that inhibits ... bronchial constriction *in vivo*," (Paper 13 at page 12). Reconsideration and withdrawal of the rejection is thus respectfully requested.

Claim Rejection Under 35 U.S.C. § 102(b):

Claims 1-5, 10-13, 16-25 and 31-32 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Huang *et al.* Applicants respectfully traverse the rejection for the following reasons. First, Huang *et al.* does not disclose a pharmaceutical composition consisting of a peptide of sequence AHWSGHCCL and a pharmaceutically acceptable carrier or diluent. As discussed at the interview, using closed "consisting of" language excludes non-pharmaceutically

acceptable carriers and excipients. At most, Huang *et al.* discloses the peptide of SEQ ID NO:1 together with immunoglobulin light chain (LC). LC is not the peptide of SEQ ID NO:1, nor is it a pharmaceutically acceptable carrier or excipient. The reference thus fails to disclose a pharmaceutical composition consisting of SEQ ID NO:1 and a pharmaceutical carrier or excipient and the anticipation rejection fails.

Reconsideration and withdrawal of the rejection is respectfully requested.

Furthermore, Huang *et al.* does not teach or suggest a pharmaceutical composition consisting of a peptide sequence and a carrier or excipient. In particular, the synthesis and purity of the peptide of Huang *et al.* was not described. The peptides are said to be synthesized by the protein core facility of ... the University of Alabama and by Research Genetics, Inc. (Huang *et al.* at page 732, second column). Therefore, Huang *et al.* provides no information regarding the purity of the peptides, the amount of residual blocking groups or solvents and reagents present in the peptide. For example, the peptide is eluted from a column using an acetonitrile gradient (Huang *et al.* at page 732, second column). Acetonitrile is metabolized to cyanide in the body. Huang *et al.* provides no information regarding the concentration of acetonitrile in the peptides. Thus, injecting the peptide of Huang *et al.* may produce unacceptable levels of cyanide.

Furthermore, the Merrifield solid-phase synthesis process (which may have been used, however, no information is provided) uses a chemical called tBoc (tertiary butyloxycarbonyl) to protect the amino terminus and various benzyl groups to protect the side chains. It's known that the benzylic side chain protecting groups in tBoc chemistry are not totally stable during the TFA treatment, which is used to remove the tBoc for the next amino acid. In the last step, a stronger acid, anhydrous hydrogen fluoride (HF), is used to cleave the peptide from the insoluble support. Huang *et al.* provides no information regarding the residual concentration of any of these toxic solvents and reagents.

Thus, a person of ordinary skill in the art would not use the peptide of Huang *et al.* as a pharmaceutical compound. The shear lack of a description regarding the method of synthesis would prevent a person of ordinary skill in the art from using the Huang *et al.* peptide. Contamination of the peptide by toxic solvents and reagents, or the presence of incomplete

deprotection of the side chains, renders the peptide of Huang *et al.* unsuitable for a pharmaceutical composition. Finally, Huang *et al.* provides no motivation to use the peptide as a pharmaceutical composition. In particular, Huang *et al.* state that the light chain binding site on THP will help produce strategies that inhibit interaction of LCs with THP ...." (Huang *et al.* at page 736, first column; emphasis added). Thus, Huang *et al.* does not provide motivation to a person of ordinary skill in the art to use a peptide as a pharmaceutical composition, only as a further research tool.

CONCLUSION

In view of the foregoing, the claims, as amended, should be in condition for allowance. Furthermore, the amendment cancels claims and removes the rejections under 35 U.S.C. § 112, first paragraph. If questions exist after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the number given below.

Respectfully submitted,

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